ÓSCAR SALAMANCA
PRESIDENT OF AECIC

"THERE WILL BE A SIGNIFICANT CHANGE IN RESEARCH AND CLINICAL TRIALS IN LESS THAN TEN YEARS"

THE EXPEDIENCY DURING THE START-UP PROCESS OF CLINICAL STUDIES MAKES SPAIN A POWERFUL COUNTRY WORLDWIDE, HIGHLIGHTS ÓSCAR SALAMANCA, PRESIDENT OF AECIC, THE ASSOCIATION THAT IS PRIMARILY FORMED BY THE CROS AND THAT IS CELEBRATING ITS 20TH ANNIVERSARY THIS YEAR. THERE ARE, HOWEVER, OBSTACLES YET TO BE OVERCOME, SUCH AS REGIONAL DISPARITY AT INFRASTRUCTURE LEVEL AND THE ORDEAL FOR PATIENTS TO GET ACCESS TO RECENTLY APPROVED DRUGS.

Clinical research and clinical trials are making unprecedented progress, which has led the *President of the Spanish Association of Clinical Research Companies in Spain (AECIC)*, **Óscar Salamanca**, to predict that, in less than a decade, a *"major change"* will have occurred in how they are managed or in the aspects needed to approve a drug. The critical driving force for this change lies with cutting-edge technologies, such as Artificial Intelligence (AI), which already enables collecting vast amounts of data from different sites and which motivates new types of design, such as basket or umbrella-type trials, focused on collecting *"a lot of patient data in a very simple way"* to make them

available *"as soon as possible"* to healthcare professionals and sponsors of clinical trials.

This new paradigm is already seen in areas such as oncology, where personalised medicine is increasingly prevalent due to the unique characteristics of each patient, making it necessary to conduct *"very specific"* trials, says Salamanca, where precise data on each patient can be recognised and collected. This was a compelling reason for the new European regulation on clinical trials implemented in January 2022.

This regulation promotes multi-centre and multinational research at European level through a single approval that is valid for all participating countries. Everything is channelled through a reference centre (following interstate mutual recognition) that conducts the evaluation and collects the information from the other participating sites. This information is centralised in the Clinical Trials Information System (CTIS). This provides access to patients needed for a trial due to the individual nature of any condition that would otherwise take much longer.

However, Salamanca highlights that a *"single and consensual"* model is needed to improve the administrative part in starting the clinical trial, an aspect in which *"work has been in progress for years"*.

In many cases, there is also the possibility of overlapping research phases II and III, as has already occurred in some drugs *"approved in phase II"* and awaiting results in phase III but which, due to their *"very good results"*, the health authorities decide to approve. There is no doubt that technology makes medicine based on Real World Data (RWD) possible, he explains, which is becoming a turning point: *"It will ensure we have real patient data, and it will not just be a patient experiment extrapolated to a population through a statistical method but instead we will have increasing access to real data"*.

Therefore, the quality of the information rather than the quantity is gaining ground in the concerns of those involved in the clinical trials (professionals, sponsors, and health authorities). It is not so much a question of increasing patient survival, but for the patient to have a good quality of life. *"Ultimately this means that, when drugs are approved, the health authorities increasingly consider patient experience, patient associations... and I think this will become more and more significant"*, he says.

Spain: mixed results

Our country is at the forefront in conducting clinical trials, and for several reasons. On one hand, there is a *"sufficient"* population of patients, there is a public hospital network that is *"acutely aware of the need to conduct clinical research"* and, on the other, there are many Spanish investigators *"who are highly renowned worldwide"*, which means Spain is selected for conducting a large number of trials. This is demonstrated based on data from the BEST project promoted by the Innovative Medicines platform and Farmaindustria: of the €1.267 million allocated to R&D in 2021, 62% (789 million) were spent on clinical trials alone, and a further 156 million on basic research.

Hospitals have, in most cases, been able to prepare for this demand, and Salamanca welcomes the fact that *"infrastructures have been put into place"* to accommodate this research, which has advanced Spain compared to the other neighbouring countries in adapting the clinical trial regulations issued by the European Commission to local regulations. AECIC thanks the authorities and, *"in particular"*, the Spanish Agency of Medicines and Medical Devices (AEMPS) for speeding up this process. *"This enables us to speed up, a very important value because time is money in the world of research,"* he says.

OF THE €1.267 MILLION ALLOCATED TO R&D IN 2021, 62% WAS SPENT ON CLINICAL TRIALS ALONE

He currently estimates that the time between collecting all the information and reaching the first patient is between 90 and 100 days, a *"very interesting"* time frame to receive all the relevant approvals and to start one of these research processes.

It also means that patients participating in these trials have access to the latest news and therapies. These are the reasons that lead Salamanca to highlight Spain as a *"leader in terms of speed and recruitment"*, particularly in highly dynamic areas in clinical research and where both investigators and scientific publications generated in Spain stand out, such as in the case of oncohaematology.

In fact, he talks of sponsors from the United States who come to Spain to *"develop all their molecules, particularly because of the time and cost involved in performing the research here compared with what is involved there. They are swamped, recruitment is not good, and the commitment here is usually fulfilled by the sites"*, he says.

If that's the good part, the bad part would lie in the abundance of health systems that make up our National Health System (NHS). Each autonomous region (AR) deploys a specific model for collecting information, which means there are up to 17 different models. In other countries, such as the Nordic countries, there are *"common databases with well-collected and structured information"* that provide them with a more complete understanding of the situation of the diseases in their context.

Therefore, Salamanca asks health officials to realise that *"the importance of health lies with everyone and does not depend on the acronyms of the political parties in charge of the regions"*.

Sad "inequality" in access

It is no secret that it takes an eternity for a drug to reach Spanish patients once approved by the European Medicines Agency (EMA). In its latest report on access to medicines from July last year, Farmaindustria set this figure at 517 days, although only a few months ago the delay stood at over 600 days. This is *"outrageous"* for Salamanca, who does not understand how it can take up to two and a half years before becoming available.

Behind this problem are the *"competing interests"*: the economic interest that the authorities put before the healthcare professional or patients' health, he believes, given that *"approval is authorised at European level, and the problem lies with the reimbursement price"*. In addition to this is the *"inequality"* of becoming ill or having a disease depending on the area. *"It may well be that you do not have access to a drug because you live in a certain region whereas 100 kilometres away you would have"*, he regrets.

AECIC (which this year celebrates its 20th anniversary) is striving to collaborate in the development of these drugs and argues that, once European approval is secured, *"it should just be a quick formality"* to obtain the reimbursement price. In Germany, which Salamanca gives as an example, a medicine that has already been approved by the EMA is *"immediately"* available to any German patient.

"TIME IS MONEY IN THE WORLD OF RESEARCH"

"It is a pity that, as one of the best places for conducting clinical research, market access for new drugs is not available to all patients. What's more, this availability depends on the different autonomous regions", Salamanca criticises.

As an association representing the interests of the Contract Research Organisations (CROs), AECIC is mainly responsible for ensuring local compliance with the European regulations enacted, in addition to promoting the attracting of "global" research to Spain or being the benchmark when explaining administrative issues to companies or consulting with the health authorities. This has resulted in the organisation becoming a player to be considered by national and EU authorities when enacting legislation.

It has an *"excellent relationship"* with sponsors such as Farmaindustria, as they share common interests to ensure the clinical trial *"is as good as possible, above all for patients"*. +